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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/290,049 04/12/99 SMITH

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021005 HM22/0314
HAMILTON BROOK SMITH AND REYNOLDS
TWO MILITIA DR
LEXINGTON MA 02421-4799

EXAMINER

LEE, L

ART UNIT

PAPER NUMBER

1645

9

DATE MAILED:

03/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/290,049

Applicant(s)
Smith et al

Examiner
Li Lee

Group Art Unit
1645



☐ Responsive to communication(s) filed on Jan 3, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-19 is/are pending in the application

Of the above, claim(s) 12-14, 18, and 19 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-11 and 15-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of group I, claims 1-11, 15-17 in Paper No. 8 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 4- 5, 7-11, 15, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1, 4- 5, 7-11, 15, 17 are indefinite as there is no defined specific amino acid sequence in the claims. Without reciting a specific amino acid sequence, one cannot isolate the protein vaccine which is specifically having particular amino acids at the particular positions in the claimed polypeptide from a glucosyltransferase due to the existence of other glucosyltransferase polypeptide in the nature and one of ordinary skill in the art would not be reasonably be apprised of the metes and bounds of the claimed subject matter.

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Claims 1, 4- 5, 7-11, 15, 17 are further indefinite for using the term “an equivalent”. It is not clearly defined what property and characteristic of the equivalency is for a particular amino acid at a particular position of a peptide sequence.

Double Patenting

5. Claims 15-17 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-2, and 4, respectively. Because the recitation of “at least one peptide” in claims 1-2 and 4 is essentially the same as the recitation of “a peptide” in claims 15-17. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Drawings

6. This application has been filed with drawings which have been approved by the draftsperson.

Information Disclosure Statement

7. Items listed on form PTO-1449 filed on Aug.. 23, 99 have be considered by the examiner. The US application No. 08/967,573 is not considered because there is no copy of the application.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiroza et al (J Bacteriol 169: 4263-4270, 1987).

Shiroza et al teach a polypeptide sequence which is 100% identical to the polypeptide sequence of SEQ ID NO:1 and SEQ ID NO:3 of the instant application.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-11 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiroza et al (J Bacteriol 169: 4263-4270, 1987) and Taubman et al (US Patent 5,686,075).

Shiroza et al teach a polypeptide sequence which is 100% identical to the polypeptide sequence of SEQ ID NO:1 and SEQ ID NO:3 of the instant application.

Shiroza et al do not expressly teach a composition comprising multivalent polypeptides. However, Taubman et al teach a multicomponent and multivalent peptides composition from glucosyltransferase. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to covalently link the peptide

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of Shiroza et al to a multivalent peptide composition as taught by Taubman et al. because the known benefit of providing effective vaccine capabilities. Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Status of Claims

12. No claims are allowed. All claims stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Li Lee
March 3, 2000

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ALBERT NAVARRO
PATENT EXAMINER